AF $1634

TRANSMITTAL OF APPEAL BRIEF (Large Entity)

Docket No.
Pha-1626

In Re Application Of: **A. Asp, et al.**

Serial No.	Filing Date	Examiner	Group Art Unit
09/970,412	**October 3, 2001**	**D. Johannsen**	**1634**

Invention: **A Kit for Use in a Method of Sequencing**

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

Transmitted herewith in triplicate is the Appeal Brief in this application, with respect to the Notice of Appeal filed on **April 10, 2003.**

The fee for filing this Appeal Brief is: **$320.00**

☐ A check in the amount of the fee is enclosed.

☒ The Commissioner has already been authorized to charge fees in this application to a Deposit Account. A duplicate copy of this sheet is enclosed.

☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 502-590
A duplicate copy of this sheet is enclosed.

Royal N. Ronning, Jr.
Signature

Dated: **June 6, 2003**

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I certify that this document and fee is being deposited on **June 6, 2003** with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

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Signature of Person Mailing Correspondence

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Typed or Printed Name of Person Mailing Correspondence

cc:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	A. Asp, et al.	Group Art Unit:	1634
Serial number:	09/970,412	Examiner:	D. Johannsen
Filing Date:	October 3, 2001		
For:	A Kit for Use in a Method of Sequencing		

APPEAL BRIEF

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

June 6, 2003

Sir:

Appellants submit this Appeal Brief in triplicate, appealing from the January 10, 2003, rejection of the Primary Examiner, finally rejecting all pending claims in the captioned application. The Notice of Appeal was filed on April 10, 2003.

REAL PARTY IN INTEREST

Amersham Biosciences AB, formerly known as Amersham Pharmacia Biotech AB, owner of the captioned application, is the real party in interest to this appeal.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences related to the instant appeal.

STATUS OF CLAIMS

Claims 11 and 12 are pending in the captioned application. These claims are reproduced in Appendix A, attached hereto.

STATUS OF AMENDMENTS

There are no outstanding amendments with respect to the captioned application.

SUMMARY OF INVENTION

The instant invention presents a process for analyzing the sequence of a polynucleotide of interest by:

a) incorporating one member of a specific binding pair at the end of each strand of a double stranded polynucleotide of interest, the number being of the same type for both strands;

b) immobilizing both strands of the polynucleotide to a solid support provided with the other member of the specific binding pair;

c) annealing sequencing primers to the immobilized strands; and

d) sequencing both strands by the chain termination method. The polynucleotide of interest is preferably amplified before or in connection with step a) and most preferably by polymerase chain reaction extension. The invention also comprises a kit for use in analyzing the sequence of a polynucleotide of interest.

Claims are directed to the kit for use in analyzing the sequence (claims 11–12).

ISSUES

1. Whether claims 11 and 12 are properly rejected under 35 U.S. C. 102 (b) as being anticipated by Apple (WO92/10589).
2. Whether claim 11 is properly rejected under 35 U.S.C. 102 (b) as being anticipated by Soderland (EP 371437).
3. Whether claim 12 is properly rejected under 35 U.S.C. 103 as being unpatentable over Soderland (EP 371437) in view of Landegren (WO94/11529).

GROUPING OF CLAIMS

All of the rejected claims in the rejection appealed hereunder stand or fall together.

ARGUMENT

1. Claims 11 and 12 are not properly rejected under 35 U.S. C. 102 (b) as being anticipated by Apple (WO92/10589).

The Examiner has rejected claims 11–12 under 35 U.S.C. § 102(b) as "being anticipated by Apple (WO92/10589; 6/92)." Specifically, the Examiner states, "the claims are drawn to kits comprising a solid support, sequencing primers, and amplification primers comprising 'one member of a specific binding pair, the member being of the same type for both primers.' " The Examiner continued, "Apple teaches

methods for amplifying and typing HLA DRbeta genes, and teaches kits comprising reagents that may be employed in his methods (p. 7-8; p. 45–50). Apple's kits comprise solid supports and primers which may be labeled or unlabeled (p. 7). Apple teaches the use of primer pairs wherein one or both primers are biotinylated (p. 34-37...); Apple therefore teaches primers that are 'differently labelled', as well as pairs of primers 'comprising one member of a specific binding pair' wherein the member is identical on each of the two primers in the pair."

The Examiner continued, "with respect to claim 12, Apple discloses the use of filters and a dot blot manifold (p. 25). With respect to the recitation in the claims of the language 'sequencing primers', the mere designation of primers as 'sequencing primers' does not further limit the primers with respect to structure or function; any primer may be employed in some manner in a method of sequencing. It is an inherent property of the primers of Apple that they could be employed in sequencing. Thus, Apple anticipates the instant claims. It is also noted that Apple teaches that sequencing may be employed in analysis of HLA DRbeta genes (p. 7, p. 24)."

In response, Appellants disagreed and submitted that the Examiner was misapplying the teachings of Apple. Specifically, Appellants conceded that kits taught by the Apple reference comprise solid supports and primers; however, they maintained there was no disclosure, nor even any suggestion, of the inclusion of both amplification and sequencing primers as required in the claims of the instant applicant. Applicants further pointed out that while the Apple reference does present a discussion of sequencing, it neither discloses nor suggests the requirement that both amplification and sequencing primers be present, as recited in the instant claims.

In response the Examiner has stated that "the instant claims are not drawn to e.g. a method requiring the steps of amplification and sequencing in which different primers are employed, but rather to a kit that includes 'two amplification primers' and 'sequencing primers'". The Examiner continues, "the mere designation of primers as 'sequencing primers' does not limit the structural or functional properties of the primers in a way that would obviate the instant rejection", noting "the instant claims are not limited to particular 'amplification primers' that possess either structural or functional properties that would render them unsuitable for use in sequencing". She continues, "it is well known in the art that amplification primers are routinely employed in sequencing" and asserts, "Applicants have not provided any evidence or arguments that would support an assertion that the primers of Apple would not function in methods of nucleic acid sequencing", concluding "it is an inherent property of the primers of Apple that they could be employed in sequencing and thereby constitute 'sequencing primers'".

In response, Appellants respectfully submit that the Examiner is reading into the Apple reference something that is not there, by combining two amplification primers with sequencing primers in the same kit. While Appellants concede that the kit disclosed by Apple does include solid supports and primers, it does not discuss including amplification and sequencing primers in it. While it further does mention sequencing, there is no disclosure or suggestion of a kit for analyzing the sequence containing these different compounds. Indeed, all the Examiner has shown is that the Apple reference discloses primers, without any reference to sequencing primers whatsoever; by suggesting that some of the primers disclosed might have some utility in sequencing, the Examiner has read into the reference something which is neither disclosed nor suggested. Such,

Appellants respectfully assert, is not the proper basis of a rejection under 35 U.S.C. § 102(b).

In view of the foregoing, Appellants respectfully submit that the Examiner's rejection cannot be sustained and should be withdrawn.

2. Claim 11 is not properly rejected under 35 U.S.C. § 102(b) as being anticipated by Soderland (EP 371437).

The Examiner has rejected claim 11 under 35 U.S.C. § 102(b) as being "clearly anticipated by Soderland (EP 371437 A2; 6/90)." Specifically, the Examiner states, "the claim is drawn to a kit comprising a solid support, sequencing primers, and amplification primers comprising 'one member of a specific binding pair, the member being of the same type for both primers.' " The Examiner continues, "Soderland teaches methods for analysis of a nucleic acid sequence comprising PCR to produce a 'DNA sample in which at least one attachment moiety has been introduced into at least one strand of specific target polynucleotide', attachment of target to a 'solid matrix coated with an attachment site to which the attachment moiety or a modification thereof can bind', and determination of the sequence of the amplified target by a method such as the chain termination method."

The Examiner further states, "the affinity pairs used for attachment of target to solid support may include 'biotin/avidin or streptavidin' and 'hapten/antibody' (col 5, lines 36–45). While Soderland states that, in embodiments employing two modified primers, 'The primers must in this case be modified with different attachment moieties', Soderland's teachings encompass the use of two different moieties that are 'of the same

type' (e.g., two different haptens with two different antibodies) (col 5, lines 1-4). Soderland teaches that sequencing primers 'may be distinct from or equal to the primer used' in amplification, teaches the use of one or 'two different sequencing primers', and teaches a variety of different labels for use in sequencing primers, including fluorescent labels."

Continuing, the Examiner states, "Soderland discloses that 'Reagents for use in practising the method of invention may be packaged in kit form', including amplification primers with 'attachment moieties and the corresponding solid supports' and sequencing primers." The Examiner further states, "with respect to the language 'the member being of the same type for both primers', it is noted that Soderland teaches the use together of primers 'of the same type', as discussed above. Furthermore, even if claim 11 were limited to primers comprising identical binding pair members, Soderland would anticipate such kits; the claim as written encompasses inclusion of any number of different primers, and is not limited to particular pairs of primers wherein both members of the pair comprise identical binding pair members."

In response, Appellants respectfully submitted that the Examiner was mischaracterizing the teachings of Soderland. Noting that, as the Examiner conceded, Soderland teaches in embodiments employing two modified primers, the primers must be modified with different attachment moieties, Appellants asserted that such is distinct from the instant claims, which recite that the member (of the specific binding pair) attached to the two amplification primers must be the "same type for both primers." Thus, the member must be part of a specific binding pair permitting attachment to the support, something neither disclosed nor even suggested by the Soderland reference.

In response to these arguments, the Examiner reiterated, "Soderland's teachings encompass the use of two different moieties that are of the same type", and that the use of "comprising" in the instant claim (claim 11) "permits the inclusion of any number and type of additional reagents". The Examiner continues, that while Appellants interpret the claim to require that the "member must be part of a specific binding pair permitting attachment to the support", "the instant claim includes no such requirement".

In response, Appellants reiterate the arguments presented above and submit that the Examiner cannot ignore the teachings of the specification in interpreting the claims. As taught in the specification of the instant application, the amplification primers comprise one member of a specific binding pair, with the member being of the same type for both primers. These amplification primers make possible the simultaneous sequencing of both strands. While Appellants are mindful that limitations of the specification are not read into the claims, the specification, Appellants respectfully assert, describes the invention and should be resorted to in interpreting the claims. In the instant situation, the disclosure of the Soderland reference is unlike and immaterial to the instant kits, and the amplification primers recited in the claims.

In view of the foregoing, Appellant respectfully asserts that the Examiner's rejection cannot be sustained and respectfully requests its reversal.

3. Claim 12 is not properly rejected under 35 U.S.C. § 103 as being unpatentable over Soderland (EP 371437) in view of Landegren (WO94/11529).

The Examiner has rejected claim 12 under 35 U.S.C. § 103(a) as "being unpatentable over Soderland (EP 371437 A2; 6/90) in view of Landegren (WO94/11529; 5/94). Specifically, the Examiner states, "claim 12 is drawn to kits comprising a solid support which 'is a manifold having a plurality of individual solid phase members', differently labeled sequencing primers, and amplification primers comprising 'one member of a specific binding pair, the member being of the same type for both primers.' " The Examiner continues, "Soderland teaches methods for analysis of a nucleic acid sequence comprising PCR to produce a 'DNA sample in which at least one attachment moiety has been introduced into at least one strand of specific target polynucleotide', attachment of target to a 'solid matrix coated with an attachment site to which the attachment moiety or a modification thereof can bind', and determination of the sequence of the amplified target by a method such as the chain termination method."

The Examiner states, "while Soderland teaches the use in his method and kits of a variety of different solid supports (microparticles, test tube, dipsticks, filters, microtitration wells), and states that 'the solid matrix can be of any format' (col 7, lines 4-20), Soderland does not disclose the use of a manifold 'having a plurality of individual solid phase members' as a solid support, or teach solid phase members 'adapted for cooperation with a corresponding set of receptacles', as required by the instant claim. Landegren teaches the use in nucleic acid sequencing of a solid support comprising a manifold..." The Examiner concludes, "in view of the teachings of Landegren, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Soderland so as to have included in Soderland's kits the manifold solid support of Landegren."

The Examiner further states, "with respect to the language 'the member being of the same type for both primers', it is again noted that Soderland teaches the use together of primers 'of the same type', as discussed above. Furthermore, even if claim 12 were limited to primers comprising identical binding pair members, the claimed kits would be obvious over the kits suggested by Soderland because the claim as written encompasses inclusion of any number of different primers, and is not limited to particular pairs of primers wherein both members of the pair comprise identical binding pair members."

In response, Appellants pointed out that the instant claims, as written, do require two amplification primers which comprise one member of a specific binding pair, the member being the same type for both primers, and noted that such is neither disclosed nor even suggested by the Soderland and Landegren references, which states that the member must be different.

In response, the Examiner states, "the Soderland reference, not the Landegren reference, teaches primers meeting the limitations of the claims", and that Landegren was cited "for its teaching of a particular type of solid support".

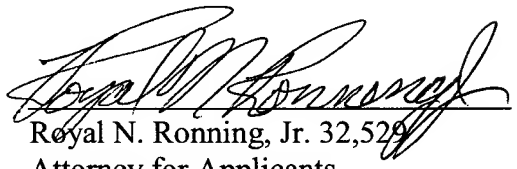
In response, Appellants reiterate the arguments presented with regard to the teachings of the Soderland reference, and respectfully assert that, by the Examiner's own admissions, the addition of the Landegren reference does nothing to remedy these deficiencies.

In view of the foregoing, Appellant respectfully asserts the Examiner's rejection cannot be sustained and respectfully requests its reversal .

CONCLUSION

In view of the foregoing, Appellant respectfully asserts that the Examiner's rejection cannot be sustained and respectfully requests the reversal of the rejection.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on June 6, 2003.

Signature: 

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APPENDIX A

The Rejected Claims

Claims 1–10 (cancelled)

Claim 11 (previously amended): A kit for use in analyzing the sequence of a polynucleotide of interest comprising:

(a) a solid support,

(b) two amplification primers comprising one member of a specific binding pair, the member being of the same type for both primers,

(c) sequencing primers.

Claim 12 (previously amended): The kit according to claim 11, wherein the solid support is a manifold having a plurality of individual solid phase members and wherein the sequencing primers are differently labelled.

Claim 13 (cancelled)